UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,807	01/22/2004	Stuart D. Shanler	136519.00101	4999

21269 7590 12/21/2009

PEPPER HAMILTON LLP
ONE MELLON CENTER, 50TH FLOOR
500 GRANT STREET
PITTSBURGH, PA 15219

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
12/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,807	SHANLER ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,13-16 and 25-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,13-16 and 25-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2009 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of September 17, 2009 made to the office action filed March 17, 2009. Claims 1, 3-6, 13-16 and 25-63 are pending. Claims 1, 3-6 and 16 are amended and claims 26-53 are new.

The Examiner did not find prior art of the elected species and thus has withdrawn the species election of the alpha-1 adrenoreceptor agonist.

In light of the amendments and Applicant's arguments, the 35 U.S.C. 103(a) rejection of claims 1-3 and 13-16 as being unpatentable over Yu et al. in view of Applicant's admitted prior art is withdrawn.

Due to the withdrawal of the previous rejection and amendments to the claims, the new rejection and objection is made below.

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Specification

The specification is objected to because the receptor type is not clear on page 23. Particularly, the alpha symbol is missing. Correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 3-6, 13-16 and 25-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of treating erythema resulting from rosacea comprising administering a composition comprising about 0.05% to about 30% of at least one alpha-1 adrenoreceptor agonist, wherein said at least one alpha-

adrenoreceptor agonist treats said erythema resulting from rosacea. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method of treating erythema resulting from rosacea in a subject in need of such treatment, comprising administering topically to the skin of said subject a composition comprising about 0.05% to about 30% of at least one alpha-1 adrenoreceptor agonist and a carrier, wherein said at least one alpha- adrenoreceptor agonist treats said erythema resulting from rosacea."

(2) The breadth of the claims:

Claims 1, 3-6, 13-16 and 25-63 embraces and reads on treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist. The specification does

not enable the treatment of erythema resulting from rosacea with any alpha-1 adrenoreceptor agonist.

(3) The state of the prior art:

The state of the art regarding effectively treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist is very low or does not exist. Friedman et al. (US 2005/0271596 A1) teach that vasoactive agents, particularly vasoconstrictors, partially treat rosacea as well as erythema (see paragraphs 65 and 87). Cunliffe et al. (British Medical Journal, 1977, p. 105) teach that the alpha2-adrenoreceptor agonist clondine, which is a known vasoconstrictor, had no effect on rosacea or the flushing associated with rosacea. Further, Fisher (West J. Med., 1995, vol. 162, pp. 123-126) teach that corticosteroid use on the face induces difficult to mange erythema and steroid rosacea (see page 123 (column 2 in its entirety). As admitted by Applicant, topical corticosteroids are know to have potent topical vasoconstrictive activity (see response filed September 17, 2009, page 9, last paragraph). Thus, it is not well known that alpha1 adrenoreceptor agonist generally are effective in treating erythema resulting from rosacea.

(4) The predictability or unpredictability of the art:

The predictability of effectively treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist is relatively low. Therefore, to one skilled in the art, treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist is

unpredictable. In other words, just because there might potentially be therapeutic targets in treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist, effective treatment has yet to be completely established. Therefore, because there is a "low potential", treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist is unpredictable.

(5) The relative skill of those in the art:

The relative skill in the art is fairly high, with the typical practitioner having a medical degree and/or an advanced degree in the biochemical, chemistry or pharmaceutical-related arts, as evidenced by Fisher, Cunliffe et al. and Friedman et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to effectively treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treat erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. Particularly, the specification teaches the mechanism and clinical use of alpha-adrenoreceptors (see pages 6-11), such as smooth muscle contraction and treatment for ocular mucosal tissue. Nevertheless, known of these mechanisms or

clinical uses are directly related to effectively and specifically treating erythema resulting from rosacea.

(7) The quantity of experimentation necessary:

The instant claims read on treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist. As discussed above the specification fails to provide any support for treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation.

Particularly, the skilled practitioner would have to test each and every one of compounds as claimed, or at least a subset that is sufficiently representative of the compounds, to determine treatment efficacy. For example, to test for treatment of the condition, a particular compound having alpha1-adrenoreceptor agonist activity, such as oxymetazoline, would have to be selected, and a suitable animal model and dosage regimen (dose amount, frequency, route of administration) would also have to be selected. If efficacy of the drug did not result, the dosage regime would have to be varied, for example by changing the dosage amount or route of administration, until efficacy was achieved. If no animal model of a condition is available for testing, then toxicity trials would have to be conducted before such testing could be conducted in humans to determine appropriate toxicity levels. If efficacy in the treatment of the condition was shown with the particular compound, then another compound having

alpha1-adrenoreceptor agonist activity would have to be selected and the process would have to be repeated, including determining the optimum dosage regimen and animal model and/or toxicity levels for evaluation. Once efficacy was established for all or a representative sample of the compounds as claimed for treating erythema resulting from rosacea with an alpha-1 adrenoreceptor agonist, the process would have to be repeated. Thus, the skilled artisan would have to undergo exhaustive studies to evaluate each compound having alpha-1 adrenoreceptor agonist activity for the treatment of erythema resulting from rosacea, in order to be able to fully carry out the invention commensurate in scope with the claims.

Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is not enabled for treating erythema resulting from rosacea with a alpha-1 adrenoreceptor agonist.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627